



[7590-01-P]

**NUCLEAR REGULATORY COMMISSION**

**10 CFR Parts 30, 32, and 35**

**[NRC-2014-0030]**

**RIN 3150-AI63**

**Medical Use of Byproduct Material - Medical Event  
Definitions and Training and Experience**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Final guidance; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing a final guidance document entitled, “Final Guidance for the Rule ‘Medical Use of Byproduct Material – Medical Events Definitions, Training and Experience, and Clarifying Amendments.’” This guidance document addresses implementation of the NRC’s final rule amending its medical use of byproduct material regulations which is being published concurrently in Separate Part IV of this issue of the *Federal Register*.

**DATES:** The guidance document is available on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Please refer to Docket ID NRC-2014-0030 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2014-0030. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdresource@nrc.gov](mailto:pdresource@nrc.gov). The final guidance document is available in ADAMS under Accession No. ML18176A377.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Donna-Beth Howe, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-5441; e-mail: [Donna-Beth.Howe@nrc.gov](mailto:Donna-Beth.Howe@nrc.gov).

**SUPPLEMENTARY INFORMATION:** The NRC published the draft guidance document in the *Federal Register* on July 21, 2014 (79 FR 42224). The NRC received seven comments on the draft guidance. The NRC's response to the public comments received can be found in the fourth section of the final guidance. The guidance document is for use by applicants, licensees, Agreement States, and the NRC staff. This guidance document (ADAMS Accession No. ML18176A377) has four parts: the first two are revisions to existing information in the NUREG-1556, "Consolidated Guidance About Materials Licenses," series of volumes for medical uses (Volume 9) and commercial nuclear pharmacies (Volume 13); the third part is a series of questions and answers to assist applicants and licensees in understanding and implementing the new regulatory changes; and the fourth is the comments received on the proposed guidance during the public comment period, and the NRC's responses. The current NUREG-1556 documents provide guidance to applicants for the completion and submission of materials license applications to the NRC. The documents also include model procedures that an applicant may consider when developing its radiation safety program. The guidance document can be found on the NRC's Medical Uses Licensee Toolkit Web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>).

The NRC is publishing concurrently with this guidance document the final rule, "Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, and Clarifying Amendments" (RIN 3150-AI63, NRC-2008-0175) in Separate Part IV of this issue of the *Federal Register*. In conjunction with the final rule, the NRC developed this final guidance document which provides guidance to licensees and applicants for implementing the revisions in the final rule.

Dated at Rockville, Maryland, this 3rd day of July, 2018.

For the Nuclear Regulatory Commission.

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